

The Honorable Ronald B. Leighton

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON AT TACOMA

PAMULA KOHLER, individually; as Personal Representative of the Estate of RICHARD A. KOHLER, JR. Decedent; and on behalf of, as Guardian, TALON KOHLER and QUINN KOHLER,)
Plaintiffs,)
v.)
SMITHKLINE BEECHAM CORPORATION)
dba GLAXOSMITHKLINE, A)
PENNSYLVANIA CORPORATION;)
Defendant.)

Case No. 3:07-cv-5697 RBL

PROTECTIVE ORDER

PROTECTIVE ORDER

1. Purpose. The parties recognize that preparation for trial of this action may require the discovery of certain documents, testimony and all other information to be disclosed. To preserve the confidentiality of such information, the parties in this action stipulate and request that a Protective Order be entered in this case as follows:

2. Confidential Information. All information obtained, derived or generated from confidential information shall likewise be considered “Confidential Information,” except to the extent such information can be obtained independently and lawfully. All documents designated as Confidential Information shall be used for the purposes of this litigation and, per agreement by the parties, in other

substantially similar litigation in which Plaintiffs' counsel represent individuals alleging Paxil-induced suicidality or self-harm.

Confidential information includes the following three types of documents:

- (a) Documents in the Paxil® ("Paxil") New Drug Application ("NDA") and any supplemental NDAs that contain trade secrets, other confidential research, proprietary, development and commercial information and information made confidential pursuant to Federal statute or regulation. GSK will treat the appropriate Paxil NDA and supplemental NDA documents as confidential information. For individual documents produced from the NDA, GSK shall make good faith determinations whether such documents should be designated "confidential" under the terms of this Order, giving due regard to the United States Food and Drug Administration's ("FDA") public release policies and procedures, other federal and state laws regarding trade secrets, proprietary information, freedom of information, and information contained in GSK's publicly accessible website and issued through its public statements, as well as information known to exist in the public domain.
- (b) All other documents containing trade secrets, information made confidential pursuant to Federal or State statute or regulation, and other confidential and/or proprietary information that GSK or its attorneys mark as "confidential."
- (c) Documents produced by Plaintiff(s) or that have been obtained from third parties that discuss, reveal, contain or attach sensitive and confidential information, including but not limited to medical records and/or information, financial account information, social security numbers, personal diaries, personal papers and psychological records, as well as other confidential information protected from disclosure by State or Federal law.

3. Non-Disclosure of Confidential Information. Confidential Information shall not be disclosed in any way to anyone for any purpose other than as required for the preparation and trial

of this action. The dissemination of Confidential Information shall be limited to those persons designated as Qualified Persons in Paragraph 9 below. All Qualified Persons given Confidential Information shall keep all such information confidential from all other persons except as specifically provided in this Order.

4. Freedom of Information Act. Documents available to the public under the Freedom of Information Act (“FOIA”) are not confidential and not subject to this Order. In the event of a dispute as to whether a document is available through FOIA, the dispute shall be resolved by the Court.

5. Designation of Confidential Information. All documents and materials that the producing party tenders to counsel for the receiving party and designates “Confidential” by the terms of this Order shall be treated as Confidential Information from the time of the tender. A party producing documents or serving written discovery requests that contain Confidential Information shall mark such documents with the word “Confidential” to signify that they contain information believed to be subject to protection. Such marking will not obscure, alter, or interfere with the legibility of the original document. Documents so marked are referred to in this Order as “Protected Documents.” Medical records obtained from third parties shall be Protected Documents notwithstanding that they are not marked with the word “Confidential.” All Protected Documents shall be treated as Confidential Information from the time of the tender. The receiving party shall preserve and protect confidential information from unauthorized disclosure throughout their possession. For purposes of this Order, the term “document” means all written, recorded or graphic material, whether produced pursuant to the Federal Rules of Civil Procedure, subpoena, by agreement or otherwise. Interrogatory answers, responses to requests for admissions, deposition transcripts and exhibits, pleadings, motions, affidavits and briefs that quote, summarize or contain materials entitled to protection may be accorded status as Protected Documents, but to the extent feasible, shall be

prepared in such a manner that the Confidential Information is bound separately from that not entitled to protection.

6. Adverse Event Information. This Order recognizes that State and/or Federal law prohibits the disclosure of any identifying information including, the name, address, institution or any other information that would lead to the identities of any patient or reporter involved in any patient's use of Paxil. GSK will redact all such information before producing any documents. Plaintiff(s) agree not to release such information to an unauthorized person should GSK inadvertently produce such protected information.

7. Qualified Persons. Confidential Information may be disclosed only to the following persons (hereinafter referred to as "Qualified Persons"):

- a. Plaintiff(s);
- b. Defendant;
- c. Counsel of record in this action and their employees (including outside copy services) who are materially assisting counsel in the preparation for trial of this action;
- d. Case-specific medical treaters, experts, and consultants utilized and/or retained by the parties whose assistance is necessary for trial preparation of this specific action or to testify at trial or any other proceeding in this action, provided that no such disclosure shall be made to any person currently employed by or who is a consultant for any competitor of Defendant or has plans to be employed or consultant for any competitor of Defendant;
- e. The Court and the Court's employees and staff;
- f. Authors or original recipients of the Confidential Information;
- g. Witnesses at a deposition or at trial in this case who are appearing for deposition or at trial in this case voluntarily or pursuant to a validly issued subpoena and who are not former or current employees of a competitor of the Defendant; and

h. Any person mutually agreed upon among the parties.

8. Qualified Persons Bound by Order. Before being given access to any Confidential Information, each Qualified Person, other than those persons identified in paragraph 7(e) and (g), above, shall be advised of the terms of this Order, shall be given a copy of this Order, shall agree in writing to be bound by the terms of this Order by signing a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A," and consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order, and in any related proceeding. Counsel for each party shall maintain a list of all Qualified Persons to whom they or their client(s) have provided any Confidential Information, which list shall be available for inspection by the Court. Nothing contained in this Order shall prohibit counsel for Plaintiff(s) from delivering Confidential Information to any of the persons referred to in paragraph 7.

9. Return of Confidential Information by Qualified Persons. Any Confidential Information distributed or disclosed to a Qualified Person other than those persons identified in paragraph 7(g), above, shall be returned to the party's counsel who provided it to the Qualified Person at the completion of the Qualified Person's consultation or representation in this case. Upon the request of the producing party or the Court, each such Qualified Person shall execute an affidavit stating that all such documents and copies thereof have been returned as required.

10. Non-Disclosure to Competitors. In no event shall any disclosure of Confidential Information be made to competitors of Defendant, or to any person who, upon reasonable and good faith inquiry could be determined to be employees or consultants of a competitor of Defendant irrespective of whether they are retained as an expert in this action.

11. Depositions. Protected Documents may be used or marked as exhibits in depositions. If deposition testimony discloses Confidential Information, counsel for the deponent or the party with whom the deponent is affiliated shall inform the deposing counsel of the confidentiality of any such

testimony not later than 15 days after receiving a copy of the deposition transcript or by making the confidential designation on the record at the deposition. Until expiration of the 15-day period, the entire deposition will be treated as subject to protection against disclosure under this Order. If no party or deponent timely designates confidential information in a deposition, then none of the transcript or its exhibits will be treated as confidential. If a designation is made, all such testimony, and each deposition transcript, recording, or portion thereof that is so designated, shall be treated as Confidential Information unless otherwise agreed to by the parties or directed by order of the Court. (A deponent is “affiliated” with a party if he or she is a past or present officer, director, shareholder, agent, employee, consultant, representative, relative, or friend of such party.)

The witness may review his or her testimony containing the Confidential Information for purposes of completing the errata sheet within thirty (30) days of receiving a copy of the deposition transcript from the court reporter but may not keep any portion of the transcript that discusses the Confidential Information. Further, the witness must return the portions of the transcript containing the Confidential Information to the court reporter once the witness has completed the errata sheet. Any documents used at the deposition which contain Confidential Information (including marked exhibits) shall not be kept or maintained by the witness (or his or her counsel) unless these individuals first agree in writing to be bound by the terms of this Order by signing a copy of the Non-Disclosure Agreement attached hereto as Exhibit “A,” and consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order, and in any related proceeding. The provisions of this paragraph do not apply to impeachment at trial.

12. Use of Confidential Information In Court. To the extent Confidential Information under this Order is submitted to the Court for any reason, the parties have agreed to file under seal documents marked “Confidential” in connection with discovery motions or other pre-trial motions or proceedings. A party seeking to file such documents under such circumstances shall, pursuant to

Local Civil Rule (W.D. Wash.) 5(g)(3), file all documents which a party seeks to have filed under seal in a sealed envelope conspicuously marked “Request for Confidentiality Pending” and containing a legend that provides substantially as follows:

“FILED UNDER SEAL - The enclosed materials are subject to a Protective Order of the United States District Court of the Western District of Washington. This envelope may not be opened without court order by any person other than the Court, Court personnel, or counsel of record of the party filing these materials.”

The envelope must be filed together with a motion requesting the Court’s leave to file the document under seal. The motion for sealing must be publicly filed and must generally identify the documents contained in the sealed envelope.

13. Disposition of Confidential Information. Upon the request of Plaintiffs, after the final conclusion of this action (including without limitation any appeals and after the time for filing all appellate proceedings has passed), the parties shall return all “case-specific” Confidential Information (defined as documents relating specifically to Plaintiffs or their case-specific medical treaters) produced by the parties in this case to counsel for the producing party, or as otherwise ordered by the Court. Additionally, upon the request of Defendant, after the final conclusion of all litigation in which Plaintiffs’ counsel represent individuals alleging Paxil-induced suicidality or self-harm (including without limitation any appeals and after the time for filing all appellate proceedings has passed), Plaintiffs shall return all Confidential information to counsel for Defendant, or as otherwise directed by the Court. The return or destruction of Confidential Information under this paragraph shall include, without limitation, all copies, and duplications thereof. The parties shall certify that all Confidential Information required to be returned or destroyed has been so returned or destroyed within 14 days of receipt of a written request for certification. Unless otherwise ordered by the

Court, counsel may retain: (1) copies of pleadings or other papers that have been filed with the Court and that contain Confidential Information; (2) their work product; and (3) official transcripts and exhibits thereto. The terms and provisions of this Order shall continue to apply to any such materials retained by counsel.

14. Security of Confidential Information. Except as specifically provided in this Order, counsel shall keep all Confidential Information and Protected Documents produced to them within their exclusive possession and control, shall take all necessary and prudent measures to maintain the confidentiality of such materials and information, and shall not permit unauthorized dissemination of such materials to anyone.

15. Subpoena by Other Courts or Agencies. If another court or an administrative agency subpoenas or orders production of Protected Documents or Confidential Information that a party has obtained under the terms of this Order, the party shall promptly notify the producing party of the pendency of such subpoena or order. The subpoenaed party shall cooperate in good faith with the producing party in facilitating the producing party's effort to intervene in the proceeding, quash the subpoena or other reasonable action to seek appropriate relief.

16. Order Survives Termination of Action. After the termination of this action by entry of a final judgment or order of dismissal, the provisions of this Order shall continue to be binding. This Order is, and shall be deemed to be, an enforceable agreement between the parties, their agents, and their attorneys. The terms of this Order may be enforced by specific performance in any court of competent jurisdiction.

17. Parties Bound by Order. This Order shall be binding upon the parties, upon their attorneys, expert witnesses, consultants, and upon their successors, executors, personal representatives, administrators, heirs, legal representatives, assigns, subsidiaries, divisions, employees, agents, independent contractors, relatives, and other persons or organizations over whom or which the

subject parties have control. The parties, their attorneys, and employees of such attorneys, and their expert witnesses, consultants, and representatives retained in connection with this action each expressly stipulates to the personal jurisdiction of this Court for purposes of any proceeding brought by a party to this action to enforce this Order.

18. No Waiver of Objections. Neither this Order nor any of the procedures described above affects or constitutes a waiver of any party's right to object to the relevancy, admissibility or discoverability of any information or document or to seek an order that discovery or admissibility be had only subject to appropriate limits or restrictions, as provided by the Federal Rules of Civil Procedure, the Federal Rules of Evidence, the Local Rules of Civil Procedure, or other applicable rules or law.

19. No Waiver of Any Privilege. This Order does not affect or constitute a waiver of any party's right to withhold or redact information protected from disclosure by the attorney-client privilege, physician-patient privilege, work product doctrine, or other applicable privilege, protection, law, or regulation, or to seek appropriate protective orders respecting documents asserted to be subject to such privilege. The parties, by producing documents in this litigation that contain the name(s) of patients or physicians, in no way waive any duties to protect the identities of patients or physicians.

Defendant may redact from any Protected Document any trade secrets or other highly confidential research, development or commercial information that it contends is not relevant to the litigation. If, after reviewing a document containing a redaction a party has a good faith basis for challenging the redaction, counsel for the parties shall initially attempt to resolve the issue through discussions. If these discussions prove unsuccessful, counsel may move for a ruling, which may require this Court's in camera inspection of a document, on the issue of whether certain information is entitled to redaction. If this Court finds that said information should remain confidential, then said

information may not be used as evidence by either party at trial or at a hearing and may not be relied upon by either parties' retained or non-retained experts. If this Court finds that said information is not confidential, and if this Court orders Defendant to produce the document without redaction, Defendant shall produce the non-redacted document.

20. Parties' Use of Own Confidential Information or Information Available From Non-Confidential Sources. Nothing in this Order shall limit a party's right to disclose or use its own information and documents to any person for any purpose, nor does it limit a party's right to disclose or use information and documents which are publicly available or available to the party through non-confidential sources (even if such information and documents are also produced by a party in this case and designated by that party as Confidential) to any person for any purpose.

21. Burden of Proof and Challenges to Confidential Information by Parties. The party designating information, documents, materials or items as confidential bears the burden of establishing confidentiality. Nothing in this Order shall constitute a waiver of any party's right to object to the designation or non-designation of a particular document as confidential. If a party contends that any document has been erroneously or improperly designated or not designated "Confidential," the document at issue shall be treated as confidential until (a) the parties reach a written agreement; or (b) this Court issues an order stating that the document is not confidential and shall not be given confidential treatment.

In the event that a party disagrees with a party's designation of any document or information as confidential or disagrees with a party's failure to designate a document or information confidential, the objecting party shall advise counsel for the designating party, in writing, of the objection and identify the document or item with sufficient specificity to permit identification. Within 15 days of receiving the objection, the designating party shall advise the objecting party's counsel whether the

designating party will change the designation of the document or item. If this cannot be resolved between the parties, then the dispute will be presented to the Court by motion.

22. Challenges to Confidential Information by Interested Members of the Public. Any interested member of the public may object to the designation or non-designation of a particular document as confidential. If an interested member of the public contends that any document has been erroneously or improperly designated or not designated “Confidential,” the document at issue shall be treated as confidential until this Court issues an order stating that the document is not confidential and shall not be given confidential treatment.

23. Inadvertent Production or Disclosure of Confidential Information. In the event that a party inadvertently produces Confidential Information, without the required “Confidential” legend, the producing party shall contact the receiving party within 30 days of the discovery of the inadvertent production, or as promptly as reasonably possible thereafter, and inform the receiving party or parties in writing of the inadvertent production and the specific material at issue. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party’s claim of confidentiality, either as to specific documents and information disclosed or on the same or related subject matter. Upon receipt of such notice, the receiving party or parties shall treat the material identified in the notice as confidential until (a) the parties agree to non-confidential treatment of the subject material, or (b) the Court, on motion of any party, issues an order addressing the appropriate treatment of the subject material.

24. Inadvertent Production or Disclosure of Privileged Information. In the event any document claimed to be privileged or subject to a claim of privilege or immunity from discovery (including but not limited to, attorney-client privilege, work product, and immunities created by Federal or State statute or regulation) is inadvertently produced, the producing party shall, within 30 days of the discovery of inadvertent production, or as promptly as reasonably possible thereafter, give

notice to the receiving party in writing of the producing party's claim of privilege or immunity from discovery. Thereafter, the receiving party shall immediately return to the producing party the original and all copies of the privileged materials, including copies of the privileged materials disseminated to other persons by the receiving party. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of privilege or immunity from discovery, either as to specific documents and information disclosed or on the same or related subject matter. In the event that the receiving party disagrees with the producing party's claim of privilege or immunity from discovery, then the receiving party shall notify the producing party within five (5) business days of receipt of the producing party's written notice of claim of privilege or immunity, and shall set forth the precise grounds upon which the receiving party's position rests. If the parties cannot resolve the matter, then the dispute will be presented to the Court by motion filed under seal. Any responses thereto shall be filed under seal as well. From the moment a party provides notice of inadvertent production, a receiving party shall not copy, distribute or otherwise use in any manner the disputed documents or information and shall instruct all persons to whom the receiving party has disseminated a copy of the documents or information that the documents or information are subject to this Order and may not be copied, distributed or otherwise used pending the motion and further notice from the Court.

25. Modification Permitted. Nothing in this Order shall prevent any party or other person from seeking modification of this Order, or from objecting to discovery that it believes to be otherwise improper.

This 13th day of February, 2009.



RONALD B. LEIGHTON
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF
WASHINGTON AT TACOMA**

PAMULA KOHLER, individually; as Personal)
Representative of the Estate of RICHARD A.)
KOHLER, JR. Decedent; and on behalf of,)
as Guardian, TALON KOHLER and)
QUINN KOHLER)
Plaintiffs,)
v.) **Case No. 3:07-cv-5697 RBL**
SMITHKLINE BEECHAM CORPORATION,)
d/b/a GLAXOSMITHKLINE, A)
PENNSYLVANIA CORPORATION)
Defendant.)
)

NON-DISCLOSURE DECLARATION

The undersigned hereby acknowledges that [Print or type full name]
_____ has read the Protective Order entered in this action, that (s)he understands the terms thereof, that (s)he agrees to be bound by such terms, and that (s)he agrees not to disclose any confidential information to any person other than as permitted by the Protective Order.

The undersigned further agrees to cooperate in the return of all Confidential Information, as defined in the Protective Order, to counsel for the party that produced it, or to cooperate in the destruction of all Confidential Information, as defined in the Protective Order, if such a request is made by counsel for the party that produced it, or as otherwise ordered by the Court.

Date: _____ Sign: _____